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## BY HAND DELIVERY AND ECF

Honorable Joseph A. Greenaway, Jr.
United States District Court for the District of New Jersey
Martin Luther King Jr. Federal Building and Courthouse
50 Walnut Street
Room 4040
Newark, New Jersey 07101

Re: In re K-Dur Antitrust Litigation, No. 01-1652 (JAG, Jr.)

MDL No. 1419

Dear Judge Greenaway:

On July 6, 2009, the Department of Justice ("DOJ") filed an *amicus* brief in the Second Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation* ("DOJ Brief"). The DOJ's brief was submitted, at the invitation of the court, in connection with the *direct purchaser* plaintiffs' appeal of an order granting summary judgment for defendants in that case. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005).

The DOJ brief proffers—for the second time<sup>1</sup>—an approach to so-called "reverse payment" patent settlements that is at odds with the prevailing standard in the Second Circuit. That standard was established in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-13 (2d Cir. 2006), *cert. denied*, 127 S. Ct. 3001 (2007), and is now binding on subsequent panels in the Second Circuit. Consequently, the Second Circuit will almost certainly reject the DOJ standard, and affirm the grant of summary judgment in the *Cipro* case.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> See Brief for the United States as Amicus Curiae, Joblove v. Barr Labs., Inc., (No. 06-830) (2007) (submitted to the U.S. Supreme Court) ("DOJ Tamoxifen Brief").

<sup>&</sup>lt;sup>2</sup> Moreover, the *Tamoxifen* standard has also been adopted by the Federal Circuit in the *Cipro* case itself. *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 2009 WL 1738658 (June 22, 2009). That decision resulted from an appeal by *indirect* purchasers from the very same summary judgment order that is now before the Second Circuit on the *direct* purchasers' appeal.

## Case 2:01-cv-01652-JAG-MCA Document 751 Filed 07/10/09 Page 2 of 3

Honorable Joseph A. Greenaway, Jr. July 10, 2009 Page 2

The DOJ's current position on reverse payment patent settlements has changed only slightly since it filed its *amicus* brief to the Supreme Court in *Tamoxifen*. *DOJ Tamoxifen Brief* at 13. We have already described the standard proffered in DOJ's *amicus* brief in *Tamoxifen*, and explained why that standard has not been adopted by any court. *See* Defendants' Opposition to Plaintiffs' Appeal of Judge Orlofsky's Summary Judgment Decision, at 24-26. For the reasons set forth below, the standard proposed by DOJ's current brief is subject to the same flaw as the similar standard proposed in its *Tamoxifen* Brief.

DOJ's current brief reiterates its position that—because of the existence of the patent reverse payment patent settlements are not per se unlawful. DOJ Brief at 19-21. DOJ's brief also reiterates its position that such settlements should be subjected to a rule of reason analysis under which the settlement is compared to the "expected" outcome of the patent case had it "been litigated" to conclusion DOJ Brief at 28. The DOJ's current brief shifts the focus of this inquiry away from the objective strength of the patent case and towards the parties' subjective expectations about the patent case. But this shift in focus would seem to make little difference. Subjective evaluations proffered by the parties to the settlement would inevitably be challenged as self-serving, and would be challenged based on evidence of the objective merits of the patent claim. Moreover, DOJ's current brief acknowledges that for a private treble-damages case, such as this one, the antitrust court would have to assess the objective patent merits and determine whether the patent holder or alleged infringer actually would have won the underlying patent case. Id. at 24-25, 31 n.13. Such an inquiry would be necessary according to DOJ in order for the plaintiff to establish that it was injured by the alleged conduct and suffered damages. See, e.g., Atlantic Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 341-44 (1990) (liability in private case requires proof of both unreasonable restraint and injury).<sup>3</sup>

As defendants noted in their opposition to plaintiffs' appeal of summary judgment in this case, *no court* has ever adopted an approach that would require the antitrust court to conduct an after-the-fact examination of the patent issues that the parties thought they had settled. *Defs' Brief* at 24-26. Such an approach is completely unworkable and undermines settlements. *Tamoxifen*, 429 F.3d at 389-90; *Asahi Glass*, 289 F. Supp. 2d at 994. Indeed, even *plaintiffs'* economic expert agreed that such an approach "makes no sense" because it would mean that the settlement did "not settle anything." *See Leffler Dep.* 41; *Leffler Rpt.*, at ¶ 57. Plaintiffs' expert agreed that the "objectively baseless" standard is preferable to retrying the patent issues as part of the antitrust case. *Leffler Dep.* 41. And Judge Orlofsky correctly rejected a standard that

<sup>&</sup>lt;sup>3</sup> DOJ now argues that this assessment should be done in connection with the defendant's rebuttal to a presumption that the reverse payment patent settlement is unlawful. As described in the DOJ brief, the presumption would operate simply to allocate the burden of proof to the defendants in the antitrust case. *See DOJ Brief* at 27 and 18 ("all legal presumptions [are] procedural device[s], not substantive law"). Previously, DOJ had not stated which party would have the burden of proof on the issue of how the patent merits compared to the settlement.

## Case 2:01-cv-01652-JAG-MCA Document 751 Filed 07/10/09 Page 3 of 3

Honorable Joseph A. Greenaway, Jr. July 10, 2009 Page 3

would require an after-the-fact relitigation of the patent merits as part of the antitrust case. *Special Master's Report* at 43-44.

Finally, there is one issue addressed in the DOJ's current brief that DOJ had not addressed previously—the issue of whether appellate jurisdiction lies in the Federal Circuit. DOJ Brief at 32-35. DOJ's current brief states that Federal Circuit jurisdiction turns on whether the plaintiff's "right to relief depends on resolution of a substantial question of federal patent law." Id. at 33. And DOJ argues that in an antitrust case not involving a damages claim, its proposed standard for assessing a reverse payment patent settlement would not lead to exclusive Federal Circuit jurisdiction. Id. at 34. According to DOJ, in non-damage cases, the court need not actually determine the merits of the patent case, and to the extent that it did have to address patent issues, the issues would be raised by way of defense, and not as part of plaintiffs' claims. Id. For private damages actions, however, DOJ's position is that to prove the essential elements of injury and damages, plaintiffs would have to address the merits of the patent case. That would necessarily bring private damages actions into the exclusive appellate jurisdiction of the Federal Circuit.

Consequently, whether this Court were to follow the prevailing case law standard established by the Federal, Second and Eleventh Circuits, or whether it were to adopt the views espoused by the DOJ in its current brief, the appellate jurisdiction question comes out the same way: in a private antitrust damages action like this one, any appeal will go to the Federal Circuit and be decided under Federal Circuit law. The Federal Circuit has already decided the appropriate standard for these cases. Judge Orlofsky applied that standard to this case and granted summary judgment in defendants' favor. The DOJ's recent *Cipro* brief merely confirms that Judge Orlofsky's Report and Recommendation should be adopted.

For the Court's reference, we are attaching to this letter both the DOJ's recent *amicus* brief filed this week with the Second Circuit in the *Cipro* case, and DOJ's 2007 *amicus* brief filed with the Supreme Court in *Tamoxifen*.

Sincerely,

John W. Milds Gr.
John W. Nields, Jr.

cc: Plaintiffs' Lead Counsel Counsel for Defendants